General

Guideline Title

Clinical policy: procedural sedation and analgesia in the emergency department.

Bibliographic Source(s)

Godwin SA, Burton JH, Gerardo CJ, Hatten BW, Mace SE, Silvers SM, Fesmire FM, American College of Emergency Physicians. Clinical policy: procedural sedation and analgesia in the emergency department. Ann Emerg Med. 2014 Feb;63(2):247-58. [97 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Godwin SA, Caro DA, Wolf SJ, Jagoda AS, Charles R, Marett BE, Moore J, American College of Emergency Physicians. Clinical policy: procedural sedation and analgesia in the emergency department. Ann Emerg Med. 2005 Feb;45(2):177-96. [72 references]

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- March 22, 2016 – Opioid pain medicines : The U.S. Food and Drug Administration (FDA) is warning about several safety issues with the entire class of opioid pain medicines. These safety risks are potentially harmful interactions with numerous other medications, problems with the adrenal glands, and decreased sex hormone levels. They are requiring changes to the labels of all opioid drugs to warn about these risks.

Recommendations

Major Recommendations

Definitions for the strength of evidence (Class I-III) and strength of recommendations (Level A-C) are repeated at the end of the Major Recommendations.

1. In patients undergoing procedural sedation and analgesia in the emergency department (ED), does preprocedural fasting demonstrate a reduction in the risk of emesis or aspiration?
   Level A recommendations. None specified.

   Level B recommendations. Do not delay procedural sedation in adults or pediatrics in the ED based on fasting time. Preprocedural fasting for any duration has not demonstrated a reduction in the risk of emesis or aspiration when administering procedural sedation and analgesia.

   Level C recommendations. None specified.

2. In patients undergoing procedural sedation and analgesia in the ED, does the routine use of capnography reduce the incidence of adverse respiratory events?
   Level A recommendations. None specified.

   Level B recommendations. Capnography* may be used as an adjunct to pulse oximetry and clinical assessment to detect hypoventilation and apnea earlier than pulse oximetry and/or clinical assessment alone in patients undergoing procedural sedation and analgesia in the ED.

   *Capnography includes all forms of quantitative exhaled carbon dioxide analysis.

   Level C recommendations. None specified

3. In patients undergoing procedural sedation and analgesia in the ED, what is the minimum number of personnel necessary to manage complications?
   Level A recommendations. None specified.

   Level B recommendations. None specified.

   Level C recommendations. During procedural sedation and analgesia, a nurse or other qualified individual should be present for continuous monitoring of the patient, in addition to the provider performing the procedure. Physicians who are working or consulting in the ED should coordinate procedures requiring procedural sedation and analgesia with the ED staff.

4. In patients undergoing procedural sedation and analgesia in the ED, can ketamine, propofol, etomidate, dexmedetomidine, alfentanil, and remifentanil be safely administered?
   Level A recommendations. Ketamine can be safely administered to children for procedural sedation and analgesia in the ED. Propofol can be safely administered to children and adults for procedural sedation and analgesia in the ED.

   Level B recommendations. Etomidate can be safely administered to adults for procedural sedation and analgesia in the ED. A combination of propofol and ketamine can be safely administered to children and adults for procedural sedation and analgesia.

   Level C recommendations. Ketamine can be safely administered to adults for procedural sedation and analgesia in the ED. Alfentanil can be safely administered to adults for procedural sedation and analgesia in the ED. Etomidate can be safely administered to children for procedural sedation and analgesia in the ED.

Definitions:

Strength of Evidence

Literature Classification Schema*

Design/Class	Therapy†	Diagnosis‡	Prognosis§
1	Randomized, controlled trial or meta-analysis of randomized trials	Prospective cohort using a criterion standard or meta-analysis of prospective studies	Population prospective cohort or meta-analysis of prospective studies
2	Nonrandomized trial	Retrospective observational	Retrospective cohort Case control
3	Case series Case report	Case series Case report	Case series Case report

Design/Class	Therapy†	Diagnosis‡	Prognosis§
	Other (e.g., consensus, review)	Other (e.g., consensus, review)	Other (e.g., consensus, review)

*Some designs (e.g., surveys) will not fit this schema and should be assessed individually.

†Objective is to measure therapeutic efficacy comparing interventions.

‡Objective is to determine the sensitivity and specificity of diagnostic tests.

§Objective is to predict outcome including mortality and morbidity.

Approach to Downgrading Strength of Evidence*

	Design/Class		
Downgrading	1	2	3
None	I	II	III
1 level	II	III	X
2 levels	III	X	X
Fatally flawed	X	X	X

*See the "Description of Methods Used to Analyze the Evidence" field for more information.

Strength of recommendations regarding each critical question were made by subcommittee members using results from strength of evidence grading, expert opinion, and consensus among subcommittee members according to the following guidelines:

Strength of Recommendations

Level A recommendations. Generally accepted principles for patient care that reflect a high degree of clinical certainty (i.e., based on evidence from 1 or more Class of Evidence I or multiple Class of Evidence II studies).

Level B recommendations. Recommendations for patient care that may identify a particular strategy or range of strategies that reflect moderate clinical certainty (i.e., based on evidence from 1 or more Class of Evidence II studies or strong consensus of Class of Evidence III studies).

Level C recommendations. Recommendations for patient care that are based on evidence from Class of Evidence III studies or, in the absence of any adequate published literature, based on expert consensus. In instances in which consensus recommendations are made, "consensus" is placed in parentheses at the end of the recommendation.

There are certain circumstances in which the recommendations stemming from a body of evidence should not be rated as highly as the individual studies on which they are based. Factors such as heterogeneity of results, uncertainty about effect magnitude and consequences, and publication bias, among others, might lead to such a downgrading of recommendations.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Emergent and urgent conditions that require procedural sedation with or without analgesia in the emergency department (ED)

Guideline Category

Evaluation

Management

Risk Assessment

Clinical Specialty

Anesthesiology

Emergency Medicine

Pediatrics

Intended Users

Physicians

Guideline Objective(s)

- To update the 2005 clinical policy evaluating critical questions related to procedural sedation in the emergency department (ED)
- To offer a summary of recent concepts, agents, and developments in procedural sedation and analgesia
- To address the following critical questions:
    - In patients undergoing procedural sedation and analgesia in the ED, does preprocedural fasting demonstrate a reduction in the risk of emesis or aspiration?
    - In patients undergoing procedural sedation and analgesia in the ED, does the routine use of capnography reduce the incidence of adverse respiratory events?
    - In patients undergoing procedural sedation and analgesia in the ED, what is the minimum number of personnel necessary to manage complications?
    - In patients undergoing procedural sedation and analgesia in the ED, can ketamine, propofol, etomidate, dexmedetomidine, alfentanil and remifentanil be safely administered?

Target Population

- Patients of all ages in the emergency department (ED) who have emergent or urgent conditions that require pain and/or anxiety management to successfully accomplish an interventional or diagnostic procedure
- High-risk patients (e.g., those with underlying cardiopulmonary disorders, multiple trauma, head trauma, who have ingested a central nervous system depressant such as alcohol), with the understanding that these patients are at increased risk of complications from procedural sedation and analgesia

Note: This guidelines is not intended for use in:

Patients receiving inhalational anesthetics
Patients who receive analgesia for pain control without sedatives
Patients who receive sedation solely for the purpose of managing anxiolysis and behavioral emergencies
Patients who are intubated

Interventions and Practices Considered

1. Avoiding delay of procedural sedation for fasting
2. Capnography (as an adjunct to pulse oximetry and clinical assessment) to detect hypoventilation and apnea

3. Continuous monitoring of the patient by a nurse or qualified individual
4. Coordination of procedures in the emergency department (ED) requiring procedural sedation and analgesia with the ED staff
5. Sedation and analgesia with ketamine, etomidate, propofol, ketofol, or alfentanil

Major Outcomes Considered

- Patient safety considerations for procedural sedation and analgesia in the emergency department (ED)
- Safety and efficacy of a variety of agents for procedural sedation and analgesia in the ED
- Incidence and severity of respiratory adverse events leading to serious patient-centered outcomes, such as aspiration, unplanned intubation, cardiac arrest
- Drug dosages administered
- Sedation time
- Recovery time
- Patient and staff satisfaction

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

This clinical policy was created after careful review and critical analysis of the medical literature. Searches of MEDLINE, MEDLINE InProcess, Cochrane Systematic Review Database, and Cochrane Database of Clinical Trials were performed. All searches were limited to English-language sources, human studies, pediatrics, and adults. Specific key words/phrases and years used in the searches are identified under each critical question in the original guideline document. In addition, relevant articles from the bibliographies of included studies and more recent articles identified by committee members and reviewers were included.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Strength of Evidence

Literature Classification Schema*

Design/Class	Therapy†	Diagnosis‡	Prognosis§

Design/Class	Therapy†	Diagnosis‡	Prognosis§
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*Some designs (e.g., surveys) will not fit this schema and should be assessed individually.

†Objective is to measure therapeutic efficacy comparing interventions.

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Approach to Downgrading Strength of Evidence*

	Design/Class		
Downgrading	1	2	3
None	I	II	III
1 level	II	III	X
2 levels	III	X	X
Fatally flawed	X	X	X

*See the "Description of Methods Used to Analyze the Evidence" field for more information.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

All articles used in the formulation of this clinical policy were graded by at least 2 subcommittee members and assigned a Class of Evidence. In doing so, subcommittee members assigned design classes to each article, with design 1 representing the strongest study design and subsequent design classes (e.g., design 2, design 3) representing respectively weaker study designs for therapeutic, diagnostic, or prognostic clinical reports, or meta-analyses (see the "Rating Scheme for the Strength of the Evidence" field). Articles were then graded on dimensions related to the study's methodological features, including but not necessarily limited to randomization processes, blinding, allocation concealment, methods of data collection, outcome measures and their assessment, selection and misclassification biases, sample size, and generalizability. Using predetermined formulas related to the study's design, methodological quality, and applicability to the critical question, articles received a final Class of Evidence grade (i.e., Class I, Class II, Class III, or Class X) (see Appendix B in the original guideline document). Articles identified with fatal flaws or that were not applicable to the critical question received a Class of Evidence grade "X" and were not used in formulating recommendations for this policy. Grading was done with respect to the specific critical questions; thus, the level of evidence for any one study may vary according to the question. As such, it was possible for a single article to receive different Classes of Evidence as different critical questions were answered from the

same study. Question-specific Classes of Evidence grading may be found in the Evidentiary Table at the end of the original guideline document.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

This policy is a product of the American College of Emergency Physicians (ACEP) clinical policy development process, including expert review, and is based on the existing literature; where literature was not available, consensus of emergency physicians was used.

Rating Scheme for the Strength of the Recommendations

Strength of recommendations regarding each critical question were made by subcommittee members using results from strength of evidence grading, expert opinion, and consensus among subcommittee members according to the following guidelines:

Strength of Recommendations

Level A recommendations. Generally accepted principles for patient care that reflect a high degree of clinical certainty (i.e., based on evidence from 1 or more Class of Evidence I or multiple Class of Evidence II studies).

Level B recommendations. Recommendations for patient care that may identify a particular strategy or range of strategies that reflect moderate clinical certainty (i.e., based on evidence from 1 or more Class of Evidence II studies or strong consensus of Class of Evidence III studies).

Level C recommendations. Recommendations for patient care that are based on evidence from Class of Evidence III studies or, in the absence of any adequate published literature, based on expert consensus. In instances in which consensus recommendations are made, "consensus" is placed in parentheses at the end of the recommendation.

There are certain circumstances in which the recommendations stemming from a body of evidence should not be rated as highly as the individual studies on which they are based. Factors such as heterogeneity of results, uncertainty about effect magnitude and consequences, and publication bias, among others, might lead to such a downgrading of recommendations.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Expert review comments were received from emergency physicians, pediatric emergency physicians, toxicologists, a pediatric anesthesiologist, a pharmacist, and individual members of the American Academy of Pediatrics, the American College of Medical Toxicology, American College of Emergency Physicians' (ACEP) Emergency Medicine Practice Committee, Medical-Legal Committee, and Pediatric Emergency Medicine Committee, ACEP's Toxicology Section, and ACEP's Emergency Medicine Workforce Section. The draft was also open to comments from ACEP membership through *EM Today*. Their responses were used to further refine and enhance this policy; however, their responses do not imply endorsement of this clinical policy.

This clinical policy was approved by the ACEP Board of Directors, October 11, 2013.

This guideline was endorsed by the Emergency Nurses Association, December 6, 2013.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Appropriate management of patients requiring procedural sedation and analgesia in the emergency department (ED)
- Appropriate monitoring of patients requiring procedural sedation and analgesia in the ED
- Avoidance of unnecessary delays for fasting prior to performance of procedural sedation in the ED, thus enabling more rapid patient management
- Appropriate and safe administration of moderate and deep sedatives used in procedural sedation in the ED
- Agents propofol and ketamine have been combined in studies in an effort to maximize benefits and limit unwanted side effects. Propofol-associated hypotension and respiratory depression can theoretically be reduced with increases in circulatory norepinephrine induced by ketamine. Similarly, the relatively greater risks for ketamine associated nausea and emergence reactions are theoretically reduced by the antiemetic and anxiolytic properties of propofol.

Potential Harms

- Detectable respiratory events such as hypoxia, respiratory depression, and/or apnea are common and can be precursors of more serious events during procedural sedation and analgesia.
- One disadvantage of etomidate use during procedural sedation is etomidate-associated myoclonus.
- Intravenous ketamine use in the adult population remains less common than in children, likely because of reported rates of emergence phenomena, including recovery agitation.

Qualifying Statements

Qualifying Statements

- Policy statements and clinical policies are the official policies of the American College of Emergency Physicians (ACEP) and, as such, are not subject to the same peer review process as articles appearing in the journal. Policy statements and clinical policies of ACEP do not necessarily reflect the policies and beliefs of *Annals of Emergency Medicine* and its editors.
- This policy is not intended to be a complete manual on the evaluation and management of patients undergoing procedural sedation and analgesia but rather a focused examination of critical issues that have particular relevance to the current practice of emergency medicine.
- It is the goal of the Clinical Policies Committee to provide an evidence-based recommendation when the medical literature provides enough quality information to answer a critical question. When the medical literature does not contain adequate empirical data to answer a critical question, the members of the Clinical Policies Committee believe that it is equally important to alert emergency physicians to this fact.
- Recommendations offered in this policy are not intended to represent the only diagnostic and management options available to the emergency physician. ACEP clearly recognizes the importance of the individual physician's judgment and patient preferences. Rather, this guideline defines for the physician those strategies for which medical literature exists to provide support for answers to the crucial questions addressed in this policy.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Safety

Identifying Information and Availability

Bibliographic Source(s)

Godwin SA, Burton JH, Gerardo CJ, Hatten BW, Mace SE, Silvers SM, Fesmire FM, American College of Emergency Physicians. Clinical policy: procedural sedation and analgesia in the emergency department. Ann Emerg Med. 2014 Feb;63(2):247-58. [97 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2005 Feb (revised 2014 Feb)

Guideline Developer(s)

American College of Emergency Physicians - Medical Specialty Society

Source(s) of Funding

American College of Emergency Physicians

Guideline Committee

American College of Emergency Physicians Clinical Policies Subcommittee (Writing Committee) on Procedural Sedation and Analgesia

Composition of Group That Authored the Guideline

Writing Committee Members: Steven A. Godwin, MD (*Subcommittee Chair*); John H. Burton, MD; Charles J. Gerardo, MD; Benjamin W. Hatten, MD; Sharon E. Mace, MD; Scott M. Silvers, MD; Francis M. Fesmire, MD (*Committee Chair*)

Oversight Committee Members: Francis M. Fesmire, MD (*Chair 2011-2013*); Douglas Bernstein, MD (EMRA Representative 2011-2013); Deena Brecher, MSN, RN, APN, ACNS-BC, CEN, CPEN (ENA Representative 2012-2013); Michael D. Brown, MD, MSc; John H. Burton, MD; Deborah B. Diercks, MD, MSc; Steven A. Godwin, MD; Sigrid A. Hahn, MD; Jason S. Haukoos, MD, MSc (*Methodologist*); J. Stephen Huff, MD; Bruce M. Lo, MD, CPE, RDMS; Sharon E. Mace, MD; Edward R. Melnick, MD; Devorah J. Nazarian, MD; Susan B. Promes, MD; Richard D. Shih, MD; Scott M. Silvers, MD; Stephen J. Wolf, MD; Stephen V. Cantrill, MD (Liaison with Quality and Performance Committee); Robert E. O'Connor, MD, MPH (Board Liaison 2010-2013); Rhonda R. Whitson, RHIA, Staff Liaison, Clinical Policies Committee and Subcommittees

Financial Disclosures/Conflicts of Interest

Relevant industry relationships: Dr. Mace has received research grants through the Cleveland Clinic from Baxter, Gebaurer Company, Luitpold Pharmaceutics, Venaxis, and Regency Therapeutics.

Relevant industry relationships are those relationships with companies associated with products or services that significantly impact the specific aspect of disease addressed in the critical question.

Guideline Endorser(s)

Emergency Nurses Association - Professional Association

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Godwin SA, Caro DA, Wolf SJ, Jagoda AS, Charles R, Marett BE, Moore J, American College of Emergency Physicians. Clinical policy: procedural sedation and analgesia in the emergency department. Ann Emerg Med. 2005 Feb;45(2):177-96. [72 references]

Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the American College of Emergency Physicians Web site .

Availability of Companion Documents

None available

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI on February 24, 2005. The information was verified by the guideline developer on March 28, 2005. This summary was updated by ECRI Institute on May 1, 2009 following the U.S. Food and Drug Administration advisory on antiepileptic drugs. This NGC summary was updated by ECRI Institute on March 21, 2014. The updated information was verified by the guideline developer on April 15, 2014. This summary was updated by ECRI Institute on June 2, 2016 following the U.S. Food and Drug Administration advisory on Opioid pain medicines.

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